

“Exercise and Parkinson”: The Park-in-Shape study

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We hypothesize that intensive aerobic exercise in sedentary PD patients results in clinically relevant improvements of several disease-related symptoms.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26339

Bron

Nationaal Trial Register

Aandoening

Parkinson's disease - Ziekte van Parkinson
Exercise - Bewegen

Ondersteuning

Primaire sponsor: Radboud university medical center Nijmegen, department of neurology
Overige ondersteuning: ZonMw and a private foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

UPDRS-motor score after six months

Toelichting onderzoek

Doel van het onderzoek

We hypothesize that intensive aerobic exercise in sedentary PD patients results in clinically relevant improvements of several disease-related symptoms.

Onderzoeksopzet

Assessments at baseline and after 6 months

Onderzoeksproduct en/of interventie

Aerobic exercise, exergaming; 3-5x/wk for 6 months

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 1) Idiopathic Parkinson's disease, according to the UK Brain Bank criteria, diagnosed by a neurologist
- 2) H&Y stage ≤ 2
- 3) Age 30-75 years
- 4) Sedentary lifestyle (insufficient aerobic physical activity, as defined by the current American College of Sports Medicine (ACSM) recommendations for older adults²³).
- 5) Both medicated and unmedicated patients are eligible, if they:
 - ☐ Receive a stable dopaminergic medication dose (both levo-dopa and/or a dopamine agonist are allowed) for one month before the study
 - ☐ Are unmedicated and deemed unlikely to start treatment within the next month by their treating neurologist

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 1) Use of beta-blockers
- 2) Use of anti-psychotics
- 3) Inability to cycle or perform stretching exercises due to (other) neurologic or orthopedic co-morbidities
- 4) Inability to fill out questionnaires or perform a computer task (i.e due to poor vision, inability to read Dutch (illiteracy or foreign language)
- 5) Psychiatric diseases, including major depressive disorder, severe or moderate depressive episode or any form of psychosis, diagnosed by a psychiatrist in the last year.
- 6) No internet at home
- 7) MMSE < 24
- 8) Contra-indications for aerobic exercise including diagnosed cardiac diseases (for instance but not exclusive: unstable angina, heart block, arrhythmia's, uncontrolled hypertension), diagnosed but poorly controlled diabetes mellitus or pulmonary diseases (e.g. but not

exclusive COPD, exertional asthma, pulmonary emphysema).

9) Unavailable for more than 10% (approximately 2.5 weeks) of the 6 months

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2014
Aantal proefpersonen:	130
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	14-08-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44535
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4575
NTR-old	NTR4743
CCMO	NL47747.091.14
OMON	NL-OMON44535

Resultaten